OCT 2 4 2000

K002284

510(k) SUMMARY

Invacare Corporation's
Venture IDD Oxygen Conserving Device

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Contact Person:
Edward A. Kroll
Director, TQM and Regulatory Affairs

Date Prepared: July 26, 2000
Name of Device and Name/Address of Sponsor
Venture IDD Oxygen Conserving Device

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6000
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Common or Usual Name
Oxygen Conserver, Oxygen Demand Device

Classification Name
Ventilator, Non Continuous

Predicate Devices
Invacare Model IPD Oxygen Conserving Device (953852)
Medisonic Oxygen Flow Controller (K923660)
DeVilbiss Pulsair OMS (K890141)
Chad Oxymatic (K844562)

Intended Use
The intended function and use of the Invacare Venture IDD Oxygen Conserving Device is to interface with continuous flow oxygen delivery systems and conserve oxygen by sensing patient inhalation and delivering oxygen only during the inspiratory phase.

Technological Characteristics and Substantial Equivalence

A. Device Description

The Invacare Model Venture IDD Oxygen Conserving Device is a portable, battery powered, electrically operated device designed for use with continuous flow oxygen delivery systems. It's intended function and use is to interface with continuous flow oxygen delivery systems and conserve oxygen by sensing patient inhalation and delivering oxygen only during the inspiratory phase.

The device is available in both 20 psig and 50 psig versions, depending on the output pressure of the source gas delivery system with which it is used. It consists basically of an enclosure, a printed circuit board (PCB), a solenoid valve, a mass flow sensor and an alkaline D cell battery. During standard pulsing operation, a valve receives a signal from the microprocessor to open and allow oxygen to flow.

The mass flow sensor detects the inspiratory phase of breathing. The battery provides power to the device during standard operation. The battery is mounted in a compartment accessible to the user from the back of the unit.

External to the housing is the control used to activate the device and the status indicators, which display the relative status of the device. Status indicators include green, yellow and red light emitting diodes (led's). The green led will illuminate with each patient breath as an indicator that the Invacare Model Venture IDD Oxygen Conserving Device is properly functioning.

The device also includes a fail safe and alarm feature used to alert the user of system malfunction or lack of a detectable patient inhalation. Should the patient not initiate a detectable breath, the unit enters "Default Pulsing Mode" automatically.

B. Substantial Equivalence

The Invacare Model Venture IDD Oxygen Conserving Device is substantially equivalent to the Invacare Model IPD Oxygen Conserving Device (953852), the Medisonic Oxygen Flow Controller (K923660), the DeVilbiss Pulsair OMS (K890141), and the Chad Oxymatic (K844562).

Performance Data

The Invacare Model Venture IDD Oxygen Conserving Device was tested in accordance with the electrical, mechanical and environmental performance requirements for home use respiratory devices set forth in the Anesthesiology and Respiratory Devices Branch's November 1993 document entitled "Reviewer Guidance for Premarket Notification Submissions ", published by the Anesthesiology and Respiratory Devices Branch. In all instances the device met the required performance criteria and functioned as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2002

Mr. Edward A. Kroll
Invacare Corporation
One Invacare Way
P.O. Box 4028
Elyria, OH 44036-2125

Re: K002284
Model Venture IDD Oxygen Conserving Device
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II (two)
Product Code: 73 NFB

Dear Mr. Kroll:

This letter corrects our substantially equivalent letter of October 24, 2000, regarding the Model Venture IDD Oxygen Conserving Device. Our letter identified the product code as 73 BZD. This is in error; the correct product code is 73 NFB as indicated above.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): *TBD* K002284

Device Name: *Venture IDD Oxygen Conserving Device*

Indications For Use:
The intended function and use of the Invacare Venture IDD Oxygen Conserving Device is to interface with continuous flow oxygen delivery systems and conserve oxygen by sensing patient inhalation and delivering oxygen only during the inspiratory phase. It is intended for use in the home, or in an extended care environment.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002284

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)